DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2015

Rachel's Remedies, LLC
Mrs. Rachel E. Jackson
2316 Delaware Ave.
#174
Buffalo, New York 14216

Re: K150139
Trade Name: Rachel's Remedy
Regulation Number: 21 CFR 890.5730
Regulation Name: Moist heat pack
Regulatory Class: Class I
Product Code: IMA, IMD
Dated: April 16, 2015
Received: April 22, 2015

Dear Mrs. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150139

Device Name

Rachel's Remedy

Indications for Use *(Describe)*

Rachel's Remedy is designed to provide moist heat and/or cooling relief to relieve symptoms associated with clogged ducts, mastitis, milk blisters, blebs and engorgement. It is also designed to encourage let-down and milk flow, and can help prevent mastitis.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary K150139

Prepared on May 19, 2015

Trade Name:	Rachel's Remedy
Contact Person:	Rachel E. Jackson
Title:	President
Address:	542 Parkside Avenue, Buffalo, New York 14216
Phone:	716-362-0237
Fax:	716-362-0246
Email:	rachel@rachelsremedy.com
Establishment Registration:	Submitting within 30 days of 510(k) submission
Regulation Number:	Classification 890.5730
Device Class:	I
Common Name, Device:	Moist Heat Pack
Product Code:	IMA
Regulation Medical Specialty:	Physical Medicine
Review Panel:	Physical Medicine

Intended Use:

Rachel's Remedy is designed to provide moist heat and/or cooling relief to relieve symptoms associated with clogged ducts, mastitis, milk blisters, blebs and engorgement. It is also designed to encourage let-down and milk flow, and can help to prevent mastitis.

Description of Device:

Rachel's Remedy is a hot/cold therapy pack composed of a 100% cotton flannel pillow filled with all natural flaxseed. It is designed to provide heating or cooling relief to soothe breastfeeding pain and discomfort. The pillow is inserted into a food-safe water-resistant pouch. There is a removable 100% organic cotton layer that may be moistened and used for moist heat, or the therapy pack may be used alone for heating and/or cooling relief. The flaxseed filled pillow can either be microwaved for heating relief, or put in the freezer for cooling relief.

Rachel's Remedy is made from materials manufactured in the United States. The removable cotton layer is 100% organic cotton, the pouch is CPSIA certified and food-safe PUL, and the flaxseed filled pillow is made from 100% cotton flannel and is filled with 100% all natural flaxseed. All of the fabrics used in Rachel's Remedy are made in the United States and are CPSIA certified and made specifically for baby products.

Predicate Device:

The following is a substantially equivalent device that is a legally marketed moist heat pack. Since our indications for use exceed this, we have submitted valid scientific evidence to support and verify our indications for use.

510(K) Number	K832803	K841698
Device Name	Steam Pak Moist Heat	Heat Pack
Applicant	Electro-Med Health Industries, Inc.	Maddak, Inc.
Regulation Number	890.5730	890.5730
Product Code	IMA	IMA
Decision Date	8/18/83	5/10/84
Decision	SE	SE
Regulation Medical Specialty	PM	PM

Equivalency of Technology

The Steam Pak Moist Heat device provides moist heat to localized areas of the body and gives approximately 30 minutes of moist heat. It contains a cotton fabric on the outside, and uses gel beads as the heating element. Rachel's Remedy also contains cotton fabric that touches the skin, but contains an all-natural flaxseed filled center as the heating element. Rachel's Remedy provides approximately 20 minutes of moist heat. The difference of the heating element between Rachel's Remedy and the Steam Pak, do not adversely affect the safety or effectiveness of the product. Both products get heated in the microwave, and have the capacity to absorb and release heat over a period of time when placed on the body. Both products use passive heat. Rachel's Remedy could potentially lose heat slightly more quickly, however the user can put it back in the microwave to heat it and reuse it if needed for a longer period of time.

Safety

The flaxseed pillow is made of 100% cotton flannel, and all materials are made in the United States. The pouch that holds the flaxseed pillow is made of CPSIA certified and food safe fabric which is food grade and certified safe for babies. It is commonly used for bibs, diapers and other baby products. Rachel's Remedy contains a removable 100% organic cotton layer that can be moistened and attached to the pouch to provide moist heat. All of the fabrics used in Rachel's Remedy are made in the United States and are specifically designed for baby products. The only part of Rachel's Remedy that would touch a breastfeeding mother's skin, is the organic cotton. There are no residues or chemicals on either of these fabrics. These fabrics pose no health risks to a nursing infant and an adult woman using Rachel's Remedy.

Performance Data:

The following peer-reviewed literature, studies and online reference materials were submitted to support each of the indications for use for Rachel's Remedy as follows: (please see the detailed discussion as to the relevancy of each article to each indication of use which was previously submitted):

1. Let Down and Milk Flow: The following are references to articles and summaries we previously submitted that support use of warm compress applications (like Rachel's Remedy) as a well-recognized method to help with let-down and increase milk flow: See: Resmy V (2014, 620); St. Lukes, F-2, F-3, F-16; Neifert 91986, 750, 756); Giugliani (2004, 2); Articles were also previously submitted from the American Academy of Pediatrics, La Leche League International and the Nursing Mothers Counsel that recommend moist heat compress applications to improve milk flow and let down.

2. Clogged Milk Ducts, Milk Blisters and Blebs: The following are references to articles and summaries we previously submitted that support use of moist heat applications (like Rachel's Remedy) before each feeding and between feedings to release a clogged/plugged duct, milk blister and bleb: Heller (2012, 1151); Walker, (2008, 269); ANJ (2009, 32); Spencer (2008, 729); Giugliani (2004, 6); Strong (2011, 783). Articles were also previously submitted from the Centers for Disease Control, the American Academy of Pediatrics, the La Leche League International, and the St. Luke's Hospital online Mother-Baby Resource Guide that recommend the use of moist heat to treat Clogged Milk Ducts.

3. Mastitis: The following are references to articles and summaries we previously submitted that support use of warm compresses (like Rachel's Remedy) to relieve symptoms of and to help prevent mastitis: Spencer (2008, 727-729); Heller (2012, 1151); Walker (2008, 721): Niefert (1986, 756-757); Foxman (2002, 105-106 113); Strong (2011, 757, 762, 783). Articles were also previously submitted from the Centers for Disease Control, the American Academy of Pediatrics, the La Leche League International, and the St. Luke's Hospital online Mother-Baby Resource guide, that recommend the use of moist heat on the breast several times per day to treat and prevent mastitis.

4. Engorgement: The following are references to articles and summaries we previously submitted that support the use of warm compresses (like Rachel's Remedy) to the breast before nursing and cool compresses (like Rachel's Remedy) applied to the breasts between feedings to relieve engorgement: Neifert (1986, 750); Strong (2011, 758); Giugliani (2004, 2), Articles were also previously submitted from the Centers for Disease Control, the American Academy of Pediatrics, the La Leche League International, and the St. Luke's Hospital online Mother-Baby Resource guide that recommend warm compresses to the breast before nursing and cool compresses between feedings to relieve engorgement.

We have tested Rachel's Remedy's heat retention by doing performance testing by placing Rachel's Remedy in the microwave, putting it in it's waterproof pouch and placing it on the body with and without moistening the removable cotton layer. Rachel's Remedy consistently maintains its warm temperature for a minimum of 20-minute intervals.

Conclusion

The above summary of nonclinical and clinical information included in this submission support the conclusion that this device is as safe and effective and performs as well as the predicate device.